CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Type or print name of person signing certification

Signature Date

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mary M. Mader, et al. Group Art Unit: 1626

Serial No.: 10/535,002 Examiner: S. Young

Filing Date: November 13, 2003

US Nat'l Entry Date: May 12, 2005 Conf. No.: 9111

For: ANTITUMOR BENZOYLSULFONAMIDES

Docket No.: X-16114

PETITION TO THE OFFICE OF PCT LEGAL ADMINISTRATION OF THE USPTO UNDER 37 C.F.R. §1.181 FOR REVIEW AND MODIFICATION OF THE GROUP DIRECTOR'S DECISION OF RESTRICTION REQUIREMENT UNDER UNITY OF INVENTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Office of PCT Legal Administration

Sir:

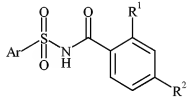
The present application entered the U.S. national phase, through the PCT, under 35 U.S.C. §371 on May 12, 2005. The present application was subjected to a restriction requirement under U.S.C. §121 and §372 on May 16, 2006. In order to be responsive, Applicants made an election, but traversed this rejection on June 16, 2006. The restriction requirement was made final with Applicants' election deemed allowable on July 14, 2006. Applicants then filed a petition on August 2, 2006 to the Technology Center Director under 37 C.F.R. §1.144 for review and modification of the restriction requirement asserting that the restriction requirement was improper. The petition was granted on October 17, 2006 as it relates to Group VI, but denied for Groups I-V. Applicants then submitted a supplemental

petition on November 3, 2006 to the Director of Technology to request the Director to reconsider the denial of the petition as it relates to Groups I-V (and all remaining material). The petition decision, denying Groups I-V, was affirmed on January 4, 2007. Applicants respectfully now petition the Office of PCT Legal Administration (Office) under 37 C.F.R. §1.181 to review the requirement for restriction in the present application, to exercise the Office's supervisory authority, and to direct the Examiner to modify the improper restriction requirement.

BACKGROUND OF THIS PETITION

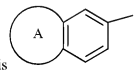
The present application relates to novel compounds that are useful as antitumor agents. See pages 23-24 of the specification as originally filed. Claims 1-5 are at issue. See claim 1 below:

1. A compound of Formula I:



I

where:

Ar is  or a heterocycle selected from the group consisting of 2,3-dihydrobenzo[1,4]dioxin-6-yl, 2,3-dihydrobenzofur-5-yl, benzo[1,3]dioxol-5-yl, 1-(C_1-C_6 alkyl)indolin-6-yl, benzothien-2-yl, benzothien-5-yl, benzothien-6-yl, 5-(C_1-C_6 alkyl)benzothien-2-yl, 6-(C_1-C_6 alkyl)benzothien-2-yl, benzothiazol-6-yl, benzofur-2-yl, benzofur-6-yl, thieno[3,2-b]pyridin-2-yl, and 1-(C_1-C_6 alkyl)indol-2-yl;

A is phenyl, benzofuryl, cyclopentadienyl, cyclobutyl, or a cyclopentyl that is optionally substituted at one of the two carbons adjacent to the ring fusion of the cyclopentyl with an oxo moiety;

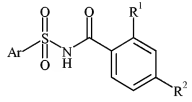
R^1 and R^2 are either both halo, both trifluoromethyl, or one is halo and the other is C_1-C_6 alkyl; or

a pharmaceutically acceptable base addition salt thereof.

2. The compound of claim 1, wherein the compound is a pharmaceutically acceptable base addition salt.

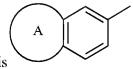
3. The compound of claim 2, wherein the pharmaceutically acceptable base addition salt is a sodium salt.

4. A method of treating susceptible neoplasms in a mammal comprising administering to a mammal in need of such treatment an oncolytically effective amount of a compound of Formula I:



I

where:

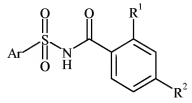
Ar is  or a heterocycle selected from the group consisting of 2,3-dihydrobenzo[1,4]dioxin-6-yl, 2,3-dihydrobenzofur-5-yl, benzo[1,3]dioxol-5-yl, 1-(C_1-C_6 alkyl)indolin-6-yl, benzothien-2-yl, benzothien-5-yl, benzothien-6-yl, 5-(C_1-C_6 alkyl)benzothien-2-yl, 6-(C_1-C_6 alkyl)benzothien-2-yl, benzothiazol-6-yl, benzofur-2-yl, benzofur-6-yl, thieno[3,2-b]pyridin-2-yl, and 1-(C_1-C_6 alkyl)indol-2-yl ;

A is phenyl , benzofuryl, cyclopentadienyl, cyclobutyl, or a cyclopentyl that is optionally substituted at one of the two carbons adjacent to the ring fusion of the cyclopentyl with an oxo moiety;

R^1 and R^2 are either both halo, both trifluoromethyl, or one is halo and the other is C_1-C_6 alkyl; or

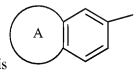
a pharmaceutically acceptable base addition salt thereof.

5. A pharmaceutical formulation comprising a compound of Formula I:



I

where:

Ar is  or a heterocycle selected from the group consisting of 2,3-dihydrobenzo[1,4]dioxin-6-yl, 2,3-dihydrobenzofur-5-yl, benzo[1,3]dioxol-5-yl, 1-(C_1-C_6 alkyl)indolin-6-yl, benzothien-2-yl, benzothien-5-yl, benzothien-6-yl, 5-(C_1-C_6 alkyl)benzothien-2-yl, 6-(C_1-C_6 alkyl)benzothien-2-yl, benzothiazol-6-yl, benzofur-2-yl, benzofur-6-yl, thieno[3,2-b]pyridin-2-yl, and 1-(C_1-C_6 alkyl)indol-2-yl ;

A is phenyl , benzofuryl, cyclopentadienyl, cyclobutyl, or a cyclopentyl that is optionally substituted at one of the two carbons adjacent to the ring fusion of the cyclopentyl with an oxo moiety;

R^1 and R^2 are either both halo, both trifluoromethyl, or one is halo and the other is C_1-C_6 alkyl; or

a pharmaceutically acceptable base addition salt thereof, and a pharmaceutically acceptable carrier, diluent, or excipient.

In the Office Action mailed on May 16, 2006, the present application was subjected to a restriction requirement between and amongst the variables from the formula of Claim 1 as well as the method claims. The Examiner indicated that restriction was required under U.S.C. §121 and §372. The Examiner asserted that the present application contains multiple inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Allegedly, a precise listing of inventive groups could not even be made due to the different classes found among the compounds of the formula (I), e.g. heterocyclic and

carbocyclic ring systems. Therefore, according to the Examiner, Applicants' claims lack unity of invention under PCT Rule 13.1 and 13.2 because the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art.

The Examiner grouped part of the genus into six *exemplary* inventions as follows:

Group I where A is phenyl, cyclopentadienyl, cyclobutyl, or cyclopentyl;

Group II where A is benzofuryl;

Group III where Ar is benzothien-2-yl, benzothien-5-yl, or benzothien-6-yl;

Group IV where Ar is thieno[3,2-b]pyridine-2-yl;

Group V where Ar is 1-(C_{1-6} alkyl)indol-2-yl; and

Group VI which is a method of use claim, Claim 4.

The Examiner stated that this list was not exhaustive, alleging that it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed to make concise groupings out of the remaining claimed subject matter.

Applicants made their election to Group III, but traversed this restriction requirement because that an improper standard for restriction had been applied.

In the next Office Action, the Examiner deemed Group III allowable and made the restriction requirement final.

Applicants petitioned the Director of Technology to direct the Examiner to modify the restriction requirement.

The Director alleged that Applicants had failed the first prong of the two-part test, "[a]ll alternatives have a common property or activity", due to a "presumption that the common property or activity asserted lies in a substituent, Ar, not the common structure, benzoylsulfonamide". The Director states:

> In this particular instance the benzoylsulfonamide group could be considered to constitute the significant structural element as it does occupy a large portion of the compound structure. However, this group is extremely well known and appears in many prior art references as the basis of sulfa drugs, etc., or as a significant structural element to which some type of group is attached in the Ar position. Thus it does not itself make a contribution over the prior art, but as noted above is not required to do so. Further, consideration of what Ar can be—a fused heterocyclic

> or non-heterocyclic structure—shows that it would be nearly as large as the benzoylsulfonamide common structure. Additionally, as applicants assert that the compounds have a common activity, it devolves that that activity must be associated with the common core or structure, which, as has been noted above, is extremely well known. However, there appears to be no indication that benzoylsulfonamides possess the antitumor activity claimed herein in the prior art which leads to the presumption that the activity is provided by the Ar substituents. In view of this conclusion Lack of Unity does exist between the different Ar groups attached to the benzoylsulfonamide structure.

The restriction was reversed as it relates to the method claim, but otherwise affirmed. Applicants filed a supplemental petition to the Director of Technology on November 3, 2006. The Director responded by stating:

> The benzoylsulfonamide structure is a structure common to all members of the Markush group and possesses pharmaceutical activity (as it is the basis for many sulfa drugs). However antitumor activity is not a known utility for benzoylsulfonamides. Therefore the benzoylsulfonamide structure does not provide Unity of Invention to the compounds of the Markush group because it does not possess the utility claimed. It was also noted that the Ar portion of the structure, which presumably provides the antitumor activity, is of relatively the same size, or occupies a similar large portion of the structure, but is variable and the structures encompassed by Ar do not have Unity of Invention due to their wide diversity. Here again, even if the benzoylsulfamide structure is considered to represent the major portion of the structure, it is so well known that it cannot form the special technical feature required that makes a contribution over the prior art. Alternatively, the benzoylsulfonamide structure may be thought to satisfy the requirement of (b)(2) in that it forms a structure which is the basis for a recognized class of chemical compounds. However, the structure is not sufficiently large or consistently defined as to meet this criterion.

And, the petition decision was affirmed.

CURRENT STATUS OF THE APPLICATION

Claims 1-5, as they relate to Group III, have been allowed. Applicants have simultaneously responded to the Examiner to amend the claims to cover the allowable material, maintaining the traversal of the restriction requirement, and filed the present petition with the Office. Applicants are planning to file a divisional for the remaining patentable subject matter.

DISCUSSION OF THE APPLICABLE PROVISIONS AS THEY RELATE TO THE DECISIONS BELOW

The position the Examiner and the Director of Technology (Director) have taken regarding unity of invention of claims 1-5 in Applicants' patent application, namely that the significant structural element must be novel, the significant structural element must have a common property or activity, and the common property or activity must already be known in the art, contradicts PCT Rule 13.1 and 13.2 and a violates PCT Article 27.

The present application is an international application which entered the U.S. national stage under 35 U.S.C. §371. When the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. §371, PCT Rule 13.1 (See attached Appendix) and 13.2 (See attached Appendix) will be followed when considering unity of invention of claims. MPEP §1850. 37 C.F.R. §1.475.

If the rule and interpretation of the PTO conflicts with the PCT, it runs afoul of Article 27 of the PCT which provides in part:

> (1) No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

See also *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. Va. 1986).

Under Section 10.11 in the PCT International Search and Preliminary Examination Guidelines, there are three particular situations for which the method for determining unity of

invention contained in Rule 13.2 is explained in greater detail. One of those situations is Markush practice.

As per Section 10.17 of the PCT International Search and Preliminary Examination Guidelines:

Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.

(a)When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; **and** (emphasis added)

(B)(1) A common structure is present, i.e. a significant structural element is shared by all of the alternatives; **or** (emphasis added)

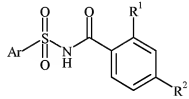
(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

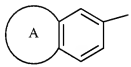
(b) In paragraph (a)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

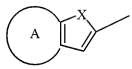
(c) In paragraph (a)(B)(2), above, the words "recognized class of chemical compounds mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted for the other, with the expectation that the same intended result would be achieved.

(d) The fact that the alternatives of a Markush grouping can be differently classified shall not, alone, be considered to be justification for a finding of a lack of unity of invention.

Applicants' claim 1 consists of a 2,4-disubstituted benzoylsulfonamide connected to a variable designated as "Ar".



Ar represents a Markush group of specific bicyclic and tricyclic aryl and heteroaryl moieties. All of the Ar substituents attach to the 2,4-disubstituted benzoyl sulfonamide core through either a phenyl, 

, or a five-membered heteroaromatic ring in which the heteroatom is in a fixed position, 

, wherein A is phenyl , benzofuryl, cyclopentadienyl, cyclobutyl, or a cyclopentyl that is optionally substituted at one of the two carbons adjacent to the ring fusion of the cyclopentyl with an oxo moiety.

As noted above, the situation involving Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is governed by PCT Rule 13.2. In this situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2 shall be considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where (1) All alternatives have a common property or activity; **and** (2) A common structure is present, i.e. a significant structural element is shared by all of the alternatives; **or** in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Applicants urge that a special technical feature exists for the formula as provided in the present application. This Markush grouping possesses a similar nature because the

alternatives for compounds of the formula provided all have the common property of being useful as antitumor agents. See pages 23-24 of the specification as originally filed. Furthermore, the claimed alternatives are of a similar nature since a common core structure occupying a large portion of all of the structures, a 2,4-disubstituted benzoylsulfonamide, is present for the claimed invention. Although not dispositive, it is worth noting that a demand was filed and a full examination conducted at the International stage of this application and the International Searching Authority did not reject the claims for lack of unity. Therefore, claims 1-5, as originally presented, meet the requirements of unity of invention.

The Director asserts that Applicants' benzoylsulfonamide **core** must provide the common activity which he instead necessarily attributes to the Ar variable, and in the response to the supplemental petition, adds that such activity must be known in the art. It appears that the Examiner and the Director have erroneously convoluted the language of PCT International Search and Preliminary Examination Guidelines Sections 10.17 (a)-(d) by mixing and matching provisions PCT International Search and Preliminary Examination Guidelines Section 10.17(a)(A) with (c) and also ignoring the plain meaning of the conditions in which a significant structural element is shared. This assertion is incorrect as a matter of science and as a matter of law.

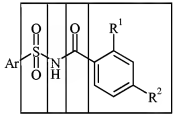
A requirement that a common core provide the common activity is technical nonsense. One of ordinary skill in the art understands that it is the compound as a whole that imparts the common activity. Activity of a radical with nothing attached cannot be assessed. It is repugnant to fundamental medicinal chemistry principles and is not in accordance with U.S. caselaw. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." *In re Papesch*, 137 USPQ 43, 51 (CCPA 1963).

Furthermore, the Director's statement, "However antitumor activity is not a known utility for benzoylsulfonamides. Therefore the benzoylsulfonamide structure does not provide Unity of Invention to the compounds of the Markush group because it does not possess the utility claimed", does not make any sense. It mandates that a radical must have known utility and because it does not possess the claimed utility, there is no unity of invention. This is absurd.

The antecedent basis for the word "**alternatives**" is the phrase "**alternatives of chemical compounds**" found in Section 10.17(a) in the PCT International Search and Preliminary Examination Guidelines, not "common structure". Thus, in order for the first prong to be met, **all alternatives of the chemical compounds** must have a common property or activity.

The Director also asserts that while Applicants' benzoylsulfonamide may provide the significant structural element it must be structurally distinctive in view of existing prior art.

In the present case, the common core consists of not only a 2,4 disubstituted phenyl but also a three-part linker of $-SO_2-$, NH, and C(O).



Applicants assert that this, the 2,4-disubstituted benzoylsulfonamide, is the common core which occupies a large portion of the structures of Applicants' compounds.

According to Section 10.17(a)(B)(1) in the PCT International Search and Preliminary Examination Guidelines, "a structurally distinctive portion in view of existing prior art" only relates to the "**or** in case the compounds have in common only a **small portion** of their structures" (emphasis added). It does not modify "a common chemical structure which occupies a large portion of their structures". This would make no sense, is in contravention to the plain meaning of the sentence in its entirety, and would greatly restrict allowable Markush practice by requiring all common cores to be novel in and of themselves.

In view of these points, Applicants assert that Claims 1-5 as originally presented, meet the criteria of unity of invention under Rules 13.1/13.2. Applicants request that the restriction requirement be removed from the present application and that Claims 1-5 be examined in their entirety. Applicants assert that the restriction required by the Examiner of Groups I-V, and maintained by the Director of Technology, does not satisfy the applicable standard and request that this petition be granted, the restriction removed, and if necessary due to possible issuance of the application in the meantime, any possible issued patent be brought back from issuance and the claims rejoined.

SUMMARY

Applicants respectfully assert that the Examiner and the Director have failed to apply the proper standard for restriction in the present application. Therefore, Applicants respectfully assert that the required restriction between Groups I through V is improper. In view of the aforementioned points, Applicants request that the Office exercise the Office's supervisory authority and direct the Examiner to modify the improper restriction requirement between Groups I through V. Specifically, Applicants request that the Office direct the Examiner to maintain the claims 1-5 in compliance with the applicable standard under 37 C.F.R. §1.475, and if necessary to do so, bring any possible issued patent back from issuance.

Respectfully submitted,

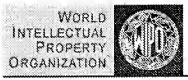
/Tina M. Tucker/
Tina M. Tucker
Attorney for Applicants
Registration No. 47,145
Phone: 317-277-3537

Eli Lilly and Company
Patent Division/TMT
P.O. Box 6288
Indianapolis, Indiana 46206-6288

January 16, 2007

Attachments:

1. PCT Rule 13.1 and 13.2
2. Chapter 10 of the PCT International Search and Preliminary Examination Guidelines



Rule 13
Unity of Invention

13.1 *Requirement*

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

13.2 *Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled*

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

13.3 *Determination of Unity of Invention Not Affected by Manner of Claiming*

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

13.4 *Dependent Claims*

Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.

13.5 *Utility Models*

Any designated State in which the grant of a utility model is sought on the basis of an international application may, instead of Rules 13.1 to 13.4, apply in respect of the matters regulated in those Rules the provisions of its national law concerning utility models once the processing of the international application has started in that State, provided that the applicant shall be allowed at least two months from the expiration of the time limit applicable under Article 22 to adapt his application to the requirements of the said provisions of the national law.

<< >> Table of Contents

Chapter 10
Unity of Invention

Determination of Unity of Invention

Article 17(3)(a); Rule 13; Section 206

10.01 An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Rule 13.2; All Annex B, Part 1(b)

10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

Rule 13.2

10.03 Lack of unity of invention may be directly evident "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity *a priori* as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known, there is lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

10.04 Although lack of unity of invention should certainly be raised in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the international search or, in accordance with Article 33(6), by any additional document considered to be relevant. If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case is considered on its merits, the benefit of any doubt being given to the applicant.

10.05 From the preceding paragraphs it is clear that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority. However, the Authority should not raise objection of lack of unity of invention merely because the inventions claimed are classified in separate classification

groups or merely for the purpose of restricting the international search to certain classification groups.

AI Annex B, Part 1(c)

10.06 Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, in a situation like the plug and socket example in paragraph 5.19, a claim to the one part referring to the other cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim.

10.07 If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. For example, suppose claim 1 claims a turbine rotor blade shaped in a specified manner, while claim 2 is for a "turbine rotor blade as claimed in claim 1" and produced from alloy Z. Then no objection under Rule 13 arises either because alloy Z was new and its composition was not obvious and thus the alloy itself already contains the essential features of an independent possibly later patentable invention, or because, although alloy Z was not new, its application in respect of turbine rotor blades was not obvious, and thus represents an independent invention in conjunction with turbine rotor blades. As another example, suppose that the main claim defines a process for the preparation of a product A starting from a product B and the second claim reads: "Process according to claim 1 characterized by producing B by a reaction using the product C." In this case, too, no objection arises under Rule 13.1, whether or not the process for preparation of B from C is novel and inventive, since claim 2 contains all the features of claim 1. The subject matter of claim 2 therefore falls within claim 1. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art and satisfies the requirement of unity of invention. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and satisfies the requirement of unity of invention and the combination claim includes all the features of the subcombination.

10.08 If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

10.09 Alternative forms of an invention may be claimed either in a plurality of independent claims, or in a single claim (but see paragraph 5.18). In the latter case, the presence of the independent alternatives may not be immediately apparent. In either case, however, the same criteria are applied in deciding whether or not there is unity of invention, and lack of unity of

invention may then also exist within a single claim. Where the claim contains distinct embodiments that are not linked by a single general inventive concept, the objection as to lack of unity of invention is raised. Rule 13.3 does not prevent an Authority from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority.

10.10 Objection of lack of unity of invention does not normally arise if the combination of a number of individual elements is claimed in a single claim (as opposed to distinct embodiments as discussed in the paragraph immediately above), even if these elements seem unrelated when considered individually (see paragraph 15.27).

Illustrations of Particular Situations

AI Annex B, Part 1(d)

10.11 There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

(i) combinations of different categories of claims;

(ii) so-called "Markush practice;" and

(iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2. Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

Combinations of Different Categories of Claims

AI Annex B, Part 1(e)

10.12 The method for determining unity of invention under Rule 13 is construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process.

A process is specially adapted for the manufacture of a product if it inherently results in the product and an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

10.13 Thus, a process is considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

10.14 Also an apparatus or means is considered "specifically designed for carrying out" a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

10.15 More extensive combinations than those set forth in paragraph 10.12 should be looked at carefully to ensure that the requirements of both Rule 13 (unity of invention) and Article 6 (conciseness of claims) are satisfied. (See paragraph 5.42 regarding conciseness of claims.) In particular, while a single set of independent claims according to one of the subparagraphs of paragraph 10.12 is always permissible, it does not require the International Authority to accept a plurality of such sets which could arise by combining the provisions of Rule 13.3 (which provides that the determination of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim), with the provisions set out in paragraph 10.12 (thus resulting in a set under paragraph 10.12 based on each of a number of independent claims in the same category under Rule 13.3 (see paragraphs 5.12 to 5.14)). The proliferation of claims arising from a combined effect of this kind should be accepted only exceptionally. For example, independent claims are permissible for two related articles such as a transmitter and receiver; however, it does not follow that, under paragraph 10.12, an applicant may include also, in the one international application, four additional independent claims: two for a process for the manufacture of the transmitter and the receiver, respectively, and two for use of the transmitter and receiver, respectively.

10.16 A single general inventive concept must link the claims in the various categories and in this connection the wording of paragraph 10.12 should be carefully noted. The link between product and process in subparagraph (i) is that the latter must be "specially adapted for the manufacture of" the former. Similarly, in paragraph 10.12, subparagraph (ii), the apparatus or means claimed must be "specifically designed for" carrying out the process. Likewise, in subparagraph (iii), the process must be "specially adapted for the manufacture of)" the product and the apparatus must be "specifically designed for" carrying out the process. In combinations (i) and (iii), the emphasis is on, and the essence of the invention should primarily reside in, the product, whereas in combination (ii) the emphasis is on, and the invention should primarily reside in, the process. (See Examples below.)

"Markush Practice"

AI Annex B, Part 1(f)

10.17 Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.

(a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(b) In paragraph (a)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

(c) In paragraph (a)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(d) The fact that the alternatives of a Markush grouping can be differently classified is not, taken alone, considered to be justification for a finding of a lack of unity of invention.

(e) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity will be raised.

(See Examples below.)

Intermediate and Final Products

AI Annex B, Part 1(g)

10.18 Rule 13.2 also governs the situation involving intermediate and final products.

(a) The term "intermediate" is intended to mean intermediate or starting products. Such products have the ability to be used to produce final products through a physical or chemical change in which the intermediate loses its identity.

(b) Unity of invention is considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

(A) the intermediate and final products have the same essential structural element, in that:

(1) the basic chemical structures of the intermediate and the final products are the same, or

(2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and

(B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

(c) Unity of invention may also be considered to be present between intermediate and final products of which the structures are not known, for example, as between an intermediate having a known structure and a final product the structure of which is not known, or as

between an intermediate of unknown structure and a final product of unknown structure. In order to satisfy unity in such cases, there must be sufficient evidence to lead one to conclude that the intermediate and final products are technically closely interrelated as, for example, when the intermediate contains the same essential element as the final product or incorporates an essential element into the final product.

(d) It is possible in a single international application to accept different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.

(e) The intermediate and final products must not be separated, in the process leading from one to the other, by an intermediate that is not new.

(f) If the same international application claims different intermediates for different structural parts of the final product, unity is not regarded as being present between the intermediates.

(g) If the intermediate and final products are families of compounds, each intermediate compound must correspond to a compound claimed in the family of the final products. However, some of the final products may have no corresponding compound in the family of the intermediate products so that the two families need not be absolutely congruent.

AI Annex B, Part 1(b)

10.19 As long as unity of invention can be recognized applying the above interpretations, the fact that, besides the ability to be used to produce final products, the intermediates also exhibit other possible effects or activities should not affect the decision on unity of invention.

Examples Concerning Unity of Invention

10.20 The application of the principles of unity of invention is illustrated by the following examples for guidance in particular cases.

Claims in Different Categories

10.21 *Example 1*

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The (method of) use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X. However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

10.22 *Example 2*

Claim 1: A process of manufacture comprising steps A and B.

Claim 2: Apparatus specifically designed for carrying out step A.

Claim 3: Apparatus specifically designed for carrying out step B.

Unity exists between claims 1 and 2 or between claims 1 and 3. There is no unity between claims 2 and 3 since there exists no common special technical feature between the two claims.

10.23 *Example 3*

Claim 1: A process for painting an article in which the paint contains a new rust inhibiting substance X including the steps of atomizing the paint using

compressed air, electrostatically charging the atomized paint using a novel electrode arrangement A and directing the paint to the article.

Claim 2: A paint containing substance X.

Claim 3: An apparatus including electrode arrangement A.

Unity exists between claims 1 and 2 where the common special technical feature is the paint containing substance X or between claims 1 and 3 where the common special technical feature is the electrode arrangement A. However, unity is lacking between claims 2 and 3 since there exists no common special technical feature between them.

10.24 *Example 4*

Claim 1: Use of a family of compounds X as insecticides.

Claim 2: Compound X_1 belonging to family X.

Provided X_1 has the insecticidal activity and the special technical feature in claim 1 is the insecticidal use, unity is present.

10.25 *Example 5*

Claim 1: A process for treating textiles comprising spraying the material with a particular coating composition under special conditions (for example, as to temperature, irradiation).

Claim 2: A textile material coated according to the process of claim 1.

Claim 3: A spraying machine for use in the process of claim 1 and characterized by a new nozzle arrangement providing a better distribution of the composition being sprayed.

The process according to claim 1 imparts unexpected properties to the product of claim 2. The special technical feature in claim 1 is the use of special process conditions corresponding to what is made necessary by the choice of the particular coating. Unity exists between claims 1 and 2. The spraying machine in claim 3 does not correspond to the above identified special technical feature. Unity does not exist between claim 3 and claims 1 and 2.

10.26 *Example 6*

Claim 1: A fuel burner with tangential fuel inlets into a mixing chamber.

Claim 2: A process for making a fuel burner including the step of forming tangential fuel inlets into a mixing chamber.

Claim 3: A process for making a fuel burner including casting step A.

Claim 4: An apparatus for carrying out a process for making a fuel burner including feature X resulting in the formation of tangential fuel inlets.

Claim 5: An apparatus for carrying out a process for making a fuel burner including a protective housing B.

Claim 6: A process of manufacturing carbon black including the step of tangentially introducing fuel into a mixing chamber of a fuel burner.

Unity exists between claims 1, 2, 4, and 6. The special technical feature common to all the claims is the tangential fuel inlets. Claims 3 and 5 lack unity with claims 1, 2, 4, and 6 since claims 3 and 5 do not include the same or corresponding special technical feature as set forth in claims 1, 2, 4, and 6. Claims 3 and 5 would also lack unity with one another.

10.27 *Example 7*

Claim 1: A high corrosion resistant and high strength ferritic stainless steel strip consisting essentially of, in percent by weight: Ni=2.0-5.0; Cr=15-19; Mo=1-2; and the balance Fe, having a thickness of between 0.5 and 2.0 mm and a 0.2% yield strength in excess of 50 kg/mm squared.

Claim 2: A method of producing a high corrosion resistant and high strength ferritic stainless steel strip consisting essentially of, in percent by weight: Ni=2.0-5.0; Cr=15-19; Mo=1-2; and the balance Fe, comprising the steps of:

(a) hot rolling to a thickness between 2.0 and 5.0 mm;

(b) annealing the hot rolled strip at 800-1000°C under substantially no oxidizing conditions;

(c) cold rolling the strip to a thickness of between 0.5 and 2.0 mm; and

(d) final annealing the cold rolled strip at between 1120 and 1200°C for a period of 2-5 minutes.

Unity exists between product claim 1 and process claim 2. The special technical feature in the product claim is the 0.2% yield strength in excess of 50 kg/mm squared. The process steps in claim 2 inherently produce a ferritic stainless steel strip with a 0.2% yield strength in excess of 50 kg/mm squared. Even if this feature is not apparent from the wording of claim 2, it is clearly disclosed in the description. Therefore said process steps are the special technical feature which correspond to the limitation in the product claim directed to the same ferritic stainless steel with the claimed strength characteristics.

Claims in the Same Category

10.28 *Example 8*

Claim 1: Plug characterized by feature A.

Claim 2: Socket characterized by corresponding feature A.

Feature A is a special technical feature that is included in both claims 1 and 2 and therefore unity is present.

10.29 *Example 9*

Claim 1: Transmitter provided with time axis expander for video signals.

Claim 2: Receiver provided with time axis compressor for video signals received.

Claim 3: Transmission equipment for video signals comprising a transmitter provided with time axis expander for video signals and a receiver provided with time axis compressor for video signals received.

The special technical features are, in claim 1 the time axis expander, and in claim 2 the time axis compressor, which are corresponding technical features. Unity exists between claims 1 and 2. Claim 3 includes both special technical features and has unity with claims 1 and 2. The requirement for unity would still be met in the absence of the combination claim (claim 3).

10.30 *Example 10*

Claim 1: Conveyor belt with feature A.

Claim 2: Conveyor belt with feature B.

Claim 3: Conveyor belt with features A + B.

Feature A is a special technical feature and feature B is another unrelated special technical feature.

Unity exists between claims 1 and 3 or between claims 2 and 3, but not between claims 1 and 2.

10.31 *Example 11*

Claim 1: Control circuit A for a d.c. motor.

Claim 2: Control circuit B for a d.c. motor.

Claim 3: An apparatus including a d.c. motor with control circuit A.

Claim 4: An apparatus including a d.c. motor with control circuit B.

Control circuit A is a special technical feature and control circuit B is another unrelated special technical feature.

Unity exists between claims 1 and 3 or between claims 2 and 4, but not between claims 1 and 2 or 3 and 4.

10.32 *Example 12*

Claim 1: A display with features A + B.

Claim 2: A display according to claim 1 with additional feature C.

Claim 3: A display with features A + B with additional feature D.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is features A + B.

10.33 *Example 13*

Claim 1: Filament A for a lamp

Claim 2: Lamp B having filament A.

Claim 3: Searchlight provided with lamp B having filament A and a swivel arrangement C.

Unity exists between claims 1, 2, and 3. The special technical feature common to all the claims is the filament A.

10.34 *Example 14*

Claim 1: A marking device for marking animals, comprising a disc-shaped element with a stem extending normally therefrom, the tip of which is designed to be driven through the skin of the animal to be marked, and a securing disk element to be fastened to the protruding tip of the stem on the other side of skin.

Claim 2: An apparatus for applying the marking device of claim 1, constructed as a pneumatically actuated gun for driving the stem of the disc-shaped element through the skin, and provided with a supporting surface adapted for taking up a securing disc element, to be placed at the other side of the body portion in question of the animal to be marked.

The special technical feature in claim 1 is the marking device having a disc-shaped element with a stem and a securing disc element to be fastened to the tip of the stem. The corresponding special technical feature in claim 2 is the pneumatically actuated gun for

driving the marking device and having a supporting surface for the securing disc element. Unity exists between claims 1 and 2.

10.35 *Example 15*

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

10.36 *Example 16*

Claim 1: An insecticide composition comprising compound A (consisting of a_1, a_2...) and a carrier.

Claim 2: Compound a_1.

All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance.

There is nevertheless still unity between the subject matter of claims 1 and 2 provided a_1 has the insecticidal activity that is also the special technical feature for compound A in claim 1.

10.37 *Example 17*

Claim 1: A chair with a lifting mechanism.

Claim 2: A chair with a mechanical screw lifting mechanism.

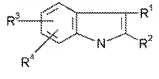
Claim 3: A chair with a hydraulic lifting mechanism.

Unity exists between claims 1-3. The special technical feature common to all the claims is the lifting mechanism. However, if any lifting mechanism is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

Markush Practice

10.38 *Example 18: Common Structure*

Claim 1: A compound of the formula:

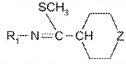


wherein R^1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R^2-R^4 are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

10.39 *Example 19: common structure:*

Claim 1: A compound of the formula:



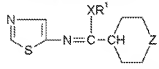
wherein R_1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; Z is selected from the group consisting of oxygen (O), sulfur (S), imino (NH), and methylene (-CH2-).

The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

In this particular case the iminothioether group -N=C-SCH3 linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.40 *Example 20: Common Structure*

Claim 1: A compound of the formula:

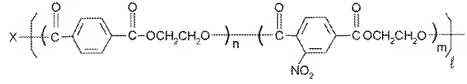


wherein R^1 is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).

The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mammalian tissue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents.

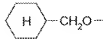
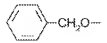
All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.41 *Example 21: Common Structure*



$1 \leq \ell \leq 10$

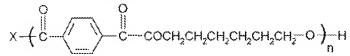
$200 \geq n + m \geq 100$

X:  *or* 

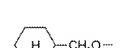
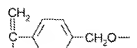
All of the above copolymers have in common a thermal degradation resistance property, due to the reduced number of free COOH radicals by esterification with X of the end COOH radicals which cause thermal degradation.

The chemical structures of the alternatives are considered to be technically closely interrelated to one another. A grouping in one claim is therefore allowed.

10.42 *Example 22: Common Structure:*



$100 \geq n \geq 50$

X:  *or* 

The compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with  *has a thermal degradation resistant property, due to the reduced number of free COOH radicals which cause thermal degradation. In contrast, the compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with a vinyl compound containing a* *moiety serves as a raw material for a setting resin when mixed with unsaturated monomer and cured (addition reaction).*

All esters covered by the claim do not have a property or activity in common. For example, the product obtained through esterification with the "$CH_2 = CH$" vinyl compound does not have a thermal degradation resistant property. The grouping in a single application is not allowed.

10.43 *Example 23: No Common Structure*

Claim 1: A herbicidal composition consisting essentially of an effective amount of the mixture of A 2,4-D(2,4-dichloro-phenoxy acetic acid) and B a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil (nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

The different components under B must be members of a recognized class of compounds. Consequently in the present case a unity objection would be raised because the members of B are not recognized as a class of compounds, but, in fact, represent a plurality of classes which may be identified as follows:

(a) inorganic salts:

copper sulfate

sodium chlorate

ammonium sulfamate

(b) organic salts and carboxylic acids:

sodium trichloroacetate

dichloropropionic acid

3-amino-2,5-dichlorobenzoic acid

(c) amides:

diphenamid

(d) nitriles:

ioxynil

(e) phenols:

dinoseb

(f) amines:

trifluralin

(g) heterocyclic:

simazine

10.44 *Example 24*

Claim 1: A pharmaceutical compound of the formula:

A – B – C – D – E

wherein:

A is selected from C_1-C_{10} alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C_5-C_7 heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C_1-C_6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C_5-C_8 ether or thioether;

C is selected from C_5-C_8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C_4-C_8 carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the various combinations. The first claimed invention would be considered to encompass the first mentioned structure for each variable, that is, A is C_1 alkyl, B is C_1 alkyl, C is a C_5 saturated heterocycle having one O heteroatom, D is C_1 alkyl, and E is a substituted phenyl.

10.45 *Example 25*

Claim 1: Catalyst for vapor phase oxidation of hydrocarbons, which consists of (X) or (X+a).

In this example (X) oxidizes RCH3 into RCH2OH and (X+a) oxidizes RCH3 further into RCOOH.

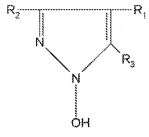
Both catalysts share a common component and a common activity as oxidation catalyst for RCH3. With (X+a) the oxidation is more complete and goes until the carboxylic acid is formed but the activity still remains the same.

A Markush grouping is acceptable in this case.

Intermediate Final Product

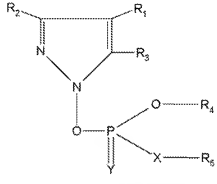
10.46 *Example 26*

Claim 1:



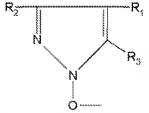
(intermediate)

Claim 2:



(final product)

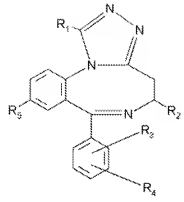
The chemical structures of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:



Therefore, unity exists between claims 1 and 2.

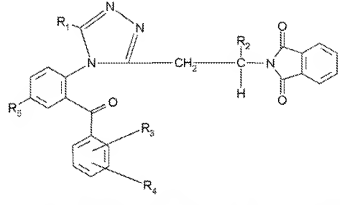
10.47 *Example 27*

Claim 1:



(I)

Claim 2:



(II)

(II) is described as an intermediate to make (I). The closure mechanism is one well known in the art. Though the basic structures of compound (I) (final product) and compound (II) (intermediate) differ considerably, compound (II) is an open ring precursor to compound (I). Both compounds share a common essential structural element that is the linkage comprising the two phenyl rings and the triazole ring. The chemical structures of the two compounds are therefore considered to be technically closely interrelated.

The example therefore satisfies the requirement for unity of invention.

10.48 *Example 28*

Claim 1: Amorphous polymer A (intermediate).

Claim 2: Crystalline polymer A (final product).

In this example a film of the amorphous polymer A is stretched to make it crystalline.

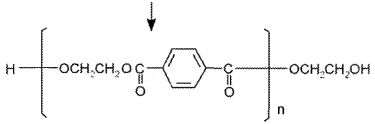
Here unity exists because there is an intermediate final product relation in that amorphous polymer A is used as a starting product to prepare crystalline polymer A.

For purposes of further illustration, assume that the polymer A in this example is polyisoprene. Here the intermediate, amorphous polyisoprene, and the final product, crystalline polyisoprene, have the same chemical structure.

10.49 *Example 29*

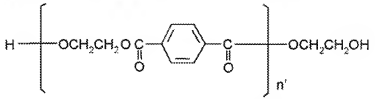
Claim 1: Polymeric compound useful as fiber material identified by the following general formula:

[repeating unit (X)]



Claim 2: Compound identified by the following general formula:

(useful as intermediate for polymeric compound I)



(primary condensation product)

The two inventions are in an intermediate and final product relationship.

Substance (II) is a raw material for substance (I).

Meanwhile, both compounds share an essential structural element (repeating unit (X)) and are technically closely interrelated. The intermediate and final products therefore satisfy the requirements for unity.

10.50 *Example 30*

Claim 1: Novel compound having structure A (Intermediate).

Claim 2: Product prepared by reacting A with a substance X (Final Product).

(see below for further details)

10.51 *Example 31*

Claim 1: Reaction product of A and B (Intermediate).

Claim 2: Product prepared by reacting the reaction product of A and B with substances X and Y (Final Product).

In examples 30 and 31 the chemical structure(s) of the intermediate and/or the final product is not known. In (30) the structure of the product of claim 2 (the final product) is not known. In (31) the structures of the products of claim 1 (the intermediate) and claim 2 (the final product) are unknown.

Unity exists if there is evidence that would lead one to conclude that the characteristic of the final product which is the inventive feature in the case is due to the intermediate. For example, the purpose for using the intermediates in Examples 30 or 31 is to modify certain properties of the final product. The evidence may be in the form of test data in the

specification showing the effect of the intermediate on the final product. If no such evidence exists then there is no unity on the basis of an intermediate-final product relationship.

Biotechnological Inventions

10.52 *Example 32: Multiple Structurally and Functionally Unrelated Polynucleotides*

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the claimed polynucleotides are 500 bp cDNAs obtained from a human liver cDNA library. The polynucleotides are structurally different and can be used as probes to obtain full-length DNAs, although there is no description of the function or biological activity of the corresponding proteins. Furthermore, the polynucleotides claimed are not homologous to each other.

There is no prior art available. A human liver cDNA library had not been established before.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the polynucleotides SEQ ID NOs: 1-10 share a common property or activity. While each sequence may serve as a probe to isolate its own respective full length DNA, due to the lack of homology between SEQ ID NOs: 1-10, a probe derived from SEQ ID NO: 1 cannot be used to isolate SEQ ID NOs: 2-10, respectively.

Moreover, since the polynucleotides are not homologous to each other, they fail to share a common structure i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. Therefore, the 10 polynucleotide molecules do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that polynucleotide fragments are derived from the same source (human liver) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention (*a priori*).

One possible grouping would be:

Inventions 1-10: Polynucleotides having SEQ ID NOs: 1-10.

10.53 *Example 33: Multiple Structurally and Functionally Related Polynucleotides*

Claim 1: An isolated polynucleotide selected from the group consisting of the nucleotide sequences SEQ ID NOs: 1-10.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The facts are the same as Example 32 except that the claimed polynucleotides all share a significant structural element and their corresponding mRNAs are expressed only in

the hepatocytes of patients with disease Y. The corresponding mRNAs are not expressed in the hepatocytes of healthy individuals.

There is no prior art available. The shared structural element had not been identified before, nor had any link been established between genes expressing mRNA containing that structural element and patients afflicted with disease Y.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description discloses that SEQ ID NOs: 1-10 share a common property, that is, expression of an mRNA present only in patients afflicted with disease Y. Moreover, SEQ ID NOs: 1-10 share a significant structural element that is essential to the common property, i.e., a probe comprising the shared structural element can detect the mRNA of patients afflicted with disease Y. Since both of these requirements are met, the group of polynucleotide molecules claimed meets the requirement of unity of invention (*a priori*).

10.54 *Example 34: Functionally Unrelated Single Nucleotide Polymorphisms (SNPs)*

Claim 1: An isolated nucleic acid molecule comprising SEQ ID NO: 1 with a single polymorphic change at one of the positions as shown below:

Polymorphism	*Position*	*Change from SEQ ID NO: 1 to:*
1	*10*	*G*
2	*27*	*A*
3	*157*	*C*
4	*234*	*T*
5	*1528*	*G*
6	*3498*	*C*
7	*13524*	*T*
8	*14692*	*A* .

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

According to the description, SEQ ID NO: 1 is 22,930 nucleotides in length. The SNPs 1-8 are not characterized, that is, no common property or activity has been disclosed.

SEQ ID NO: 1 has been described in the prior art but no specific function has been identified.

The polynucleotides of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the description fails to disclose that all of the SNPs 1-8 share a common property or activity. The fact that all point mutations are within a defined sequence (SEQ ID NO: 1) is not sufficient to establish unity of invention since SEQ ID NO: 1 has already been described in the prior art, and no functional relationship exists among the different SNPs claimed. For this reason, the SNPs of claim 1 lack unity of invention.

One possible grouping would be:

Inventions 1-8. SNPs 1-8.

10.55 *Example 35: Molecules Which Share a Common Function not Linked to a Common Structure*

Claim 1: A fusion protein comprising carrier protein X linked to a polypeptide having SEQ ID NO 1, 2, or 3.

The description discloses that carrier protein X is 1000 amino acids in length and functions to increase the stability of the fusion proteins in the blood stream. SEQ ID NOs: 1, 2, and 3 are small epitopes (10-20 residues in length) isolated from different antigenic regions of E.coli. *SEQ ID NOs: 1, 2, and 3 do not share any significant common structure.*

Both the structure of protein X and its function as a carrier protein are known in the prior art. Fusion proteins that generate an antigenic response to E. coli *are known in the prior art.*

The fusion proteins of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

In this example, the only common structure shared by the fusion proteins is carrier protein X. The fusion proteins share a common property, i.e., generation of an antibody response specific for *E. coli*. However, immunization with the carrier protein alone does not result in the common property; SEQ ID NO: 1, 2, or 3 is required for this property.

No special technical feature exists among the three fusion proteins. The fact that all the fusion proteins have a common property is not sufficient to establish unity of invention because (1) SEQ ID NOs: 1, 2, and 3, which impart the common property, do not share a significant structural element, (2) the common structure, carrier protein X, does not impart the common property, and (3) fusion proteins that generate an antigenic response specific for *E. coli* are known in the prior art.

One possible grouping would be:

Invention 1: Fusion protein comprising carrier protein X and SEQ ID NO: 1.

Invention 2: Fusion protein comprising carrier protein X and SEQ ID NO: 2.

Invention 3: Fusion protein comprising carrier protein X and SEQ ID NO: 3.

10.56 *Example 36: Multiple Nucleic Acid Molecules Which Share Common Structure and Encode Proteins with Common Property*

Claim 1: An isolated nucleic acid selected from SEQ ID NO: 1, 2, or 3.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The description discloses that the three nucleic acids encode dehydrogenases that include a conserved sequence motif defining the catalytic site and the dehydrogenase function of these proteins. The three nucleic acids were isolated from three different sources (mouse, rat, and human). The description clearly shows that these three nucleic acids are homologous based upon their overall sequence similarity (85-95% identity) at both the nucleotide and amino acid sequence levels.

The prior art describes a nucleic acid molecule isolated from monkeys, which has high sequence similarity (e.g., 90%) to SEQ ID NO: 1. The monkey nucleic acid encodes a dehydrogenase that includes the catalytic site defined by the conserved motif.

The nucleic acids of claim 1 would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity. Some Offices may regard claim 1 as a Markush grouping.

Rule 13.2 requires that the technical feature shared between the inventions defines a contribution over the prior art.

A same or corresponding technical feature shared among the claimed nucleic acid molecules resides in their common property (encoding dehydrogenases) and their shared structural element that is essential to the common property (the conserved motif). However, a nucleic acid molecule which encodes a dehydrogenase and contains the shared structural element has already been isolated from a different source (monkeys). Thus, the technical feature is not special because the functional and structural similarity between the claimed molecules cannot form the contribution that the group of inventions as a whole makes over the prior art. Therefore, unity of invention is lacking (*a posteriori*).

On the other hand, if the only prior art available disclosed a nucleic acid molecule encoding a dehydrogenase that lacked the catalytic site defined by the conserved sequence motif, the technical feature would be special and SEQ ID NOs: 1, 2, and 3 would have unity of invention.

A possible grouping would be:

Invention 1: Nucleic acid of SEQ ID NO: 1

Invention 2: Nucleic acid of SEQ ID NO: 2

Invention 3: Nucleic acid of SEQ ID NO: 3

10.57 *Example 37: DNA Encoding Receptors with Partial Structural Identity and Asserted Common Property*

Claim 1: A polynucleotide encoding a guanosine triphosphate-binding protein coupled receptor (GPCR) comprising a nucleotide sequence selected from the group consisting of the odd-numbered SEQ ID NOs from SEQ ID NO: 1 to SEQ ID NO: 2069.

The description identifies a conserved sequence of 15 amino acid residues found in several known GPCR molecules that is asserted to be essential to the GPCR function. A consensus polynucleotide sequence encoding the conserved amino acid sequence was generated. A database containing human genome sequences was searched using the consensus polynucleotide sequence. Using this system, 1035 polynucleotide sequences were identified, which are asserted to encode GPCR molecules that include the conserved sequence.

The prior art discloses human GPCR molecules that contain the conserved sequence of 15 amino acid residues, as well as the polynucleotide sequences that encode the conserved 15 amino acid sequence.

The common technical feature among the 1035 polynucleotide sequences is the consensus polynucleotide sequence that encodes the common sequence of 15 amino acid residues. This technical feature is not special because the consensus polynucleotide sequence was known and therefore cannot form the contribution that the group of inventions as a whole makes over

the prior art. Consequently, the 1035 different polynucleotides lack unity of invention (*a posteriori*).

One possible grouping would be:

Inventions 1-1035: Polynucleotides based on SEQ ID NOs: 1-2070 (odd-numbers)

If the description did not assert, or it was not readily apparent, that the conserved sequence of 15 amino acid residues was essential to the GPCR function, unity of invention could be lacking in the absence of any relevant prior art.

On the other hand, given the assertion in the description, in the absence of the prior art in the example, the groups would have had unity of invention.

10.58 *Example 38: Method of Screening and Compounds Identified by the Method*

Claim 1: A method to identify compounds that are antagonists of receptor R comprising the steps of contacting cells expressing on their outer membrane receptor R with its natural ligand; observing the binding of the ligand; contacting said cells bound to said ligand with a candidate compound selected from a library of compounds; and observing any change in the binding of the ligand.

Claim 2: Compound X, having formula 1.

Claim 3: Compound Y, having formula 2.

Claim 4: Compound Z, having formula 3.

Receptor R and its natural ligand are proposed as a drug target. Compounds that antagonise receptor R are proposed to have physiological effects that may be useful in therapeutic treatment. The aim is to identify lead compounds as a basis for further screening and testing of combinatorial libraries. A library is described as providing many possible structurally different compounds. Examples show that the method of claim 1 can be used to identify compounds affecting the physiological effect of binding of the natural ligand to the receptor. Only compounds X, Y and Z were shown to have such effects, but they do not appear to share a significant structural element. The description is silent with regard to the both the relationship between the structure and activity of the claimed compounds and the relationship between the structure of receptor R and the structure of the compounds.

Receptor R, its biological function, and its natural ligand are known in the prior art. No compounds that function as antagonists of receptor R are known.

The technical feature of method claim 1 resides in the step of observing the effect of the candidate compounds on ligand binding in a screening assay. Neither the same nor a corresponding special technical feature is present in any of compounds X, Y, or Z. No manufacturing relationship exists between the screening method and the claimed compounds. Further, the screening method is not a method of using claimed compounds X, Y, and Z. In the absence of any teaching as to the structure required for a compound to act as a receptor R antagonist, there is no single general concept that links the method to the claimed compounds. Thus, unity of invention is lacking (*a priori*).

Compounds X, Y, and Z would be regarded as having the same or corresponding technical feature if they had a common property or activity, and shared a significant structural element that is essential to the common property or activity. While compounds X, Y, and Z do share the common property of antagonising receptor R, there is no teaching as to a shared significant structural element, and hence, there is no disclosure of the same or corresponding technical feature.

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)

Invention 2: Compound X (claim 2)

Invention 3: Compound Y (claim 3)

Invention 4: Compound Z (claim 4)

10.59 *Example 39: Protein and its Encoding DNA*

Claim 1: Isolated protein X having SEQ ID NO: 1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO: 1.

There is no prior art.

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

If an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X, some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity. Examples of such a claim follow:

Isolated DNA molecule encoding protein X, or a DNA fragment thereof.

Isolated DNA molecule having SEQ ID NO: 2, or DNA molecules which hybridise to SEQ ID NO: 2 under stringent conditions.

If prior art existed teaching either protein X or the DNA encoding protein X, some Authorities might find that the same or corresponding technical feature did not make a contribution over the prior art, that is, was not a special technical feature, and therefore unity was lacking (*a posteriori*).

Process at the International Search Stage

Invitation to Pay Additional Fees

Article 17(3)(a); Rules 16, 40.2, 40.3, 42

10.60 After deciding that lack of unity exists, except in the circumstances described in paragraphs 10.64 and 10.65, the International Searching Authority informs the applicant of the lack of unity of invention by a communication, preceding (but see paragraph 10.61, below) the issuance of the international search report and written opinion of the International Searching Authority, which contains an invitation to pay additional fees (Form PCT/ISA/206). This invitation specifies the reasons (see paragraph 10.63) for which the international application is not considered as complying with the requirement of unity of invention, identifies the separate inventions and indicates the number of additional search fees and the amount to be paid. The International Searching Authority cannot consider the application withdrawn for lack of unity of invention, nor invite the applicant to amend the

claims, but informs the applicant that, if the international search report is to be drawn up in respect of those inventions present other than the first mentioned, then the additional fees must be paid within a stipulated period.

10.61 If preferred, the said invitation may be already accompanied by a notification of the result of a partial international search drawn up for those parts of the international application which relate to what is to be considered as the "first" invention. The result of the partial international search will be very useful for the applicant in deciding whether additional search fees should be paid so that further parts of the international application would be subjected to the international search. The invention(s) or group(s) of inventions, other than the one first mentioned in the claims, will be searched, subject to paragraphs 10.64 and 10.65, only if the applicant pays the additional fees. Thus, whether the lack of unity of invention is directly evident *a priori* or becomes apparent *a posteriori*, the examiner, may proceed in one of two ways: he may immediately inform the applicant of his finding and invite him to pay additional search fees (with Form PCT/ISA/206) and search or continue to search the invention first mentioned in the claims ("main invention"), or alternatively, he may carry out the search on the "main invention" and draw up a partial international search report which will be sent together with the invitation to pay additional search fees (with Form PCT/ISA/206).

10.62 Since these payments must take place within a period to be set by the International Searching Authority so as to enable the observation of the time limit for establishing the international search report set by Rule 42, the International Searching Authority should endeavor to ensure that international searches be made as early as possible after the receipt of the search copy. The International Searching Authority finally draws up the international search report and written opinion on those parts of the international application which relate to inventions in respect of which the search fee and any additional search fee have been paid. The international search report (see paragraph 16.29) and written opinion (see paragraphs 17.36 and 17.37) identify the separate inventions or groups of inventions forming unity and indicate those parts of the international application for which a search has been made. If no additional search fee has been paid, the international search report and written opinion contain only the references relating to the invention first mentioned in the claims.

Rule 40.1

10.63 In the invitation to pay additional fees, the International Searching Authority sets out a logically presented, technical reasoning containing the basic considerations behind the finding of lack of unity.

Search of Additional Inventions Without Payment of Fees

10.64 If little or no additional search effort is required, reasons of economy *may* make it advisable for the examiner, while making the search for the main invention, to search at the same time, despite the nonpayment of additional fees, one or more additional inventions in the classification units consulted for the main invention. The international search for such additional inventions will then have to be completed in any further classification units which may be relevant, when the additional search fees have been paid. This situation may occur when the lack of unity of invention is found either *a priori* or *a posteriori*.

10.65 When the examiner finds lack of unity of invention, normally, the applicant is invited to pay fees for the search of additional inventions. In exceptional circumstances, however, the examiner may be able to establish both an international search and a written opinion covering more than one invention with negligible additional work, in particular, when the inventions are conceptually very close. In those cases, the examiner may decide to complete the international search and written opinion for the additional invention(s) together with that for

the invention first mentioned. In considering the amount of work involved, the examiner should take into account the time taken to create the written opinion as well as that needed to perform the search, since even when the analysis involved as regards the search is negligible, the opposite may be the case for the written opinion of the International Searching Authority and therefore justify requesting the additional fees. If it is considered that the total additional work does not justify requesting additional fees, all results are included in the international search report without inviting the applicant to pay an additional search fee in respect of the additional inventions searched, but stating the finding of lack of unity of invention.

Protest Procedure

Rule 40.2(c)

10.66 The applicant may protest the allegation of lack of unity of invention, or that the number of required additional fees is excessive and request a refund of the additional fee(s) paid. If, and to the extent that, the International Searching Authority finds the protest justified, the fee(s) are refunded. (The additional search fees must be paid for any protest to be considered.)

Rule 40.2(c)

10.67 Protest of allegation of lack of unity is in the form of a reasoned statement accompanying payment of the additional fee, explaining why the applicant believes that the requirements of unity of invention are fulfilled and fully taking into account the reasons indicated in the invitation to pay additional fees issued by the International Searching Authority.

Rule 40.2(c)

10.68 The protest is examined by a three-member board or other special instance of the International Searching Authority or any competent higher authority, and a decision taken on it. To the extent that the applicant's protest is found to be justified, the additional fee is totally or partly reimbursed. At the request of the applicant, the texts of both the protest and the decision on it are notified to the designated Offices together with the international search report (see paragraph 10.70).

Rule 40.2(c) to (e)

10.69 Where the applicant has paid an additional fee under protest, the International Searching Authority may require the applicant also to pay a fee for the examination of the protest ("protest fee"). Details of the protest fee, if any, charged by the International Searching Authorities appear in Annex D of the *PCT Applicant's Guide*, Volume I – Introduction to the International Phase. If a protest fee is chargeable by the International Searching Authority, it is only required in a particular case after a prior review of the justification for the invitation to pay additional search fees. The review should not be made by the examiner who made the finding alone. If the invitation to pay additional fees is maintained, the applicant is invited to pay the protest fee within one month from the date of the notification to the applicant of the result of the review. The notification of the result of the review, if negative, gives a technical reasoning of that result. If the protest fee is not paid, the protest is considered withdrawn. The protest fee is refunded to the applicant under Rule 40.2(e) where the three-member board, special instance or higher authority finds that the protest was entirely justified. The applicant may, on the payment of the protest fee, supplement the reasoned statement which accompanied the protest, taking into consideration the result of the review.

Rule 40.2(c); Section 502

10.70 Where the applicant paid additional search fee(s) under protest, he is informed promptly (Form PCT/ISA/212 may be used for that purpose) of any decision about the

compliance with the requirement of unity of invention. At the same time the International Searching Authority transmits to the International Bureau a copy of the protest and of the decision thereon as well as any request by the applicant to forward the texts of both the protest and the decision thereon to the designated Offices.

Process at the International Preliminary Examination Stage

Article 34(3)(a) to (c); Rule 68

10.71 The procedure before the International Preliminary Examining Authority regarding lack of unity of invention is governed by Article 34(3)(a) to (c) and Rule 68 (see also Rule 70.13). This procedure is more fully explained in paragraphs 10.74 to 10.76. It should be noted that in most instances lack of unity of invention will have been noted and reported upon by the International Searching Authority, which will have drawn up an international search report and written opinion based on those parts of the international application relating to the invention, or unified linked group of inventions, first mentioned in the claims ("main invention"), unless the applicant has paid additional fees.

10.72 If the applicant has not availed himself of the opportunity to have the international search report issued on at least some of the other inventions, this must be taken as an indication that the applicant is prepared for the international application to proceed on the basis that it relates to the invention first mentioned in the claims as originally contained in the international application as filed.

10.73 However, whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner during international preliminary examination. In his consideration, he should take into account all the documents cited in the international search report and any additional documents considered to be relevant.

Rule 68.2, 68.3

10.74 Where the examiner finds a lack of unity of invention, a communication may, at the option of the examiner (see paragraph 10.76), be sent to the applicant, using Form PCT/IPEA/405, informing him why there is a lack of unity of invention and inviting him within a period stated in the invitation (the period may be between one and two months from the date of the invitation), either to restrict the claims or to pay an additional fee for each additional invention claimed. Where such a communication is sent, at least one possible restriction, which would avoid the objection of lack of unity of invention, is indicated by the examiner. In the invitation to pay additional fees, the examiner sets out a logically presented, technical reasoning containing the basic considerations behind the finding of lack of unity in accordance with these Guidelines.

Article 34(3)(c); Rule 68.4, 68.5

10.75 If the applicant does not comply with the invitation (by not paying the additional fees or by not restricting the claims either sufficiently or at all), the international preliminary examination report is established on those parts of the international application which relate to what appears to be the "main invention" and the examiner indicates the relevant facts in such report. In cases of doubt as to which is the main invention, the invention first mentioned in the claims is considered the main invention.

Rule 68.1, 68.3(c) to (e); Section 603

10.76 However, there are cases of lack of unity of invention where, compared with the procedure of inviting the applicant to restrict the claims or to pay additional fees (Rule 68.2), no or little additional effort is involved in establishing the international preliminary examination report for the entire international application. Then, reasons of economy may make it advisable for the examiner to avail himself of the option referred to in Rule 68.1 by

choosing not to invite the applicant to restrict the claims or to pay additional fees. In this situation, he carries out his preliminary examination and establishes the international preliminary examination report on the entire international application, but indicates, when establishing the report, his opinion that the requirement of unity of invention is not fulfilled and the reasons therefore.

Article 34(3)(c)

10.77 If the applicant timely complies with the invitation to pay additional fees even under protest, or to restrict the claims, the examiner carries out international preliminary examination on those claimed inventions for which additional fees have been paid or to which the claims have been restricted. It should be noted that "the national law of any elected State may provide that, where its national Office finds the invitation of the IPEA justified, those parts of the international application which do not relate to the main invention shall, as far as effects in that State are concerned, be considered withdrawn unless a special fee is paid by the applicant to that Office" (Article 34(3)(b)).

Protest Procedure

10.78 Where the applicant has paid an additional fee under protest, the International Preliminary Examining Authority may require the applicant also to pay a fee for the examination of the protest ("protest fee"). Details of the protest fee, if any, charged by the International Preliminary Examining Authorities appear in Annex E of the *PCT Applicant's Guide*, Volume I – Introduction to the International Phase. If a protest fee is chargeable by the International Preliminary Examining Authority, it is only required in a particular case after a prior review of the justification for the invitation to pay additional fees. The review should not be made by the examiner who made the finding alone. If the invitation to pay additional fees is maintained, the applicant is invited to pay the protest fee within one month from the date of the notification to the applicant of the result of the review. The notification of the result of the review, if negative, gives a technical reasoning of that result. If the protest fee is not paid, the protest is considered withdrawn. The protest fee is refunded to the applicant under Rule 68.3(e) where the three-member board, special instance or higher authority finds that the protest was entirely justified. The applicant may, on the payment of the protest fee, supplement the reasoned statement which accompanied the protest, taking into consideration the result of the review.